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Baudax Bio Reports Third Quarter 2022 Financial Results and Business Highlights

BX 1000 Phase II Trial Underway

BX 2000 Dose Escalation Study Progressing

ANJESO® Vials Sold to End Users Up 16% Third Quarter Year-Over-Year

USPTO Issues Note of Allowance for additional Orange Book Listable ANJESO® Patent

MALVERN, Pa., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX) (the "Company"), a pharmaceutical company focused on innovative products for hospital and related settings, today reported financial results for the three and nine months ended September 30, 2022, updated the status of the neuromuscular blocking (NMB) agent development program, provided key metrics around the ongoing commercialization of ANJESO (meloxicam) injection, and provided an overview of other corporate and financial developments.

"Our NMB agents remain on track, and we are pleased to announce that our Phase II trial for BX 1000 is underway. Additionally, BX 2000 is continuing to enroll additional cohorts into the dose escalation trial. We believe that the data from these trials will provide us with insight on which blocking agent to preferentially move forward later in 2023. We expect that planned interim analyses will provide insight regarding doses to progress for BX 1000 by early 2023. We plan to progress through later interim analyses in the first half of 2023, which we believe will validate key attributes of the product profile. BX 2000, our ultrashort acting NMB, is continuing through its dose escalation study, which we expect to complete in the second quarter of 2023. Our NMB reversal agent remains on track as well, and we expect to complete the nonclinical and manufacturing studies needed to support an IND filing for the NMB reversal agent in the first half of 2023. We are also pleased to see ANJESO sales performance reflect a modest increase of 16% in vials sold to end users in the third quarter of 2022 compared to the same prior year quarter, however increased volume to 340B hospitals and the impact of associated discounts caused revenue for the third quarter of 2022 to be lower than the same prior year quarter" said Gerri Henwood, President and CEO of Baudax Bio. "We are happy to have positive news from the United States Patent and Trademark Office on *"Methods of administering meloxicam in an intravenous bolus dose,"* which has also been filed with the FDA to be added to the Orange Book patent list."

Third Quarter 2022 and Recent Business Highlights

NMBs

- **BX1000 (IV Intermediate duration of action).** The Phase II trial for BX 1000 is underway, with planned interim analyses that the Company believes will provide insight regarding doses to progress for BX 1000 by early 2023. The Company plans to

progress through later interim analyses in the first half of 2023, which the Company believes will validate key attributes of the product profile.

- **BX2000 (IV Ultra-short duration of action).** Cohort enrollment is ongoing for the Phase I dose escalation study evaluating the safety, tolerability, and pharmacokinetics of BX 2000 in intubated healthy volunteers. This study is comprised of likely seven or eight dosing cohorts and each cohort is planned to enroll eight patients. With the first and second cohorts dosed and enrollment of the third cohort underway, the Company expects to complete enrollment of the remaining cohorts in the study in by mid-2023.

- **BX3000 (Reversal agent).** Baudax Bio expects to complete nonclinical studies and manufacturing data required to support the IND for BX3000 in the first half of 2023. Early single agent clinical trials of BX 3000 will not require intubation (placement of a breathing tube) and so would be expected to progress quickly once the IND is filed, and trials are ready to initiate. The Company believes progress towards a reversal study using BX 3000 in patients who have received BX 1000 could begin before the end of 2023.

The Company believes the data from these clinical trials for BX 1000 and BX 2000 will provide insight on which blocking agent to preferentially move forward later in 2023.

ANJESO

- **ANJESO U.S. Commercialization.** ANJESO is indicated for the management of moderate to severe pain in adults, alone or in combination with other non-NSAID analgesics. For the nine months ending September 30, 2022, ANJESO achieved net product revenue of $1.0 million. Vials sold to end-users increased in the third quarter by approximately 16% compared to the same prior year period. This increased volume included higher volume to 340B hospitals and the impact of associated discounts caused net product revenue recognized for the third quarter of 2022 to be lower than the same prior year quarter by approximately 15%.

- **ANJESO U.S Patent Allowance.** In August 2022, Baudax Bio announced that the United States Patent and Trademark Office ("USPTO") had provided a Notice of Allowance for patent application No. 16/297,095, titled "*Methods of administering intravenous meloxicam in a bolus dose*", which includes claims covering the use of multiple doses of ANJESO for the treatment of moderate to severe pain resulting in a reduction in summed pain intensity difference and also a reduction in the use of rescue analgesia 48 hours following the first dose (the "'095 Application"). Baudax Bio has filed this patent to the FDA to be added to the Orange Book.

- **Impacts from COVID-19.** The newer Omicron variants of COVID-19 as well as hospital and ambulatory surgical center (ASC) staffing issues, although beginning to stabilize, continued to impact the number of elective surgeries performed during the quarter. Cancellations of elective surgeries were primarily due to patients or ASC and hospital staff testing positive for COVID-19, as well as reduced availability of staff and level of staffing at ASC's and hospitals.

Corporate and Financial

- **Closed $6.2 Million Public Offering.** In September, Baudax Bio closed its public offering of an aggregate of 11,819,172 shares of its common stock (or pre-funded warrants in lieu thereof), together with accompanying common stock purchase warrants, at a public offering price of $0.525 per share (or pre-funded warrant) and accompanying warrants. The gross proceeds from the offering, before deducting H.C. Wainwright & Co.'s placement agent fees and other offering expenses, were approximately $6.2 million. The Company intends to use the net proceeds from this offering for pipeline development activities and general corporate purposes.

- **Distribution of Series B Preferred Stock.** Also in September, Baudax Bio's Board of Directors declared a dividend of one one-thousandth of a share of newly designated Series B Preferred Stock, par value $0.01 per share, for each outstanding share of the Company's common stock held of record as of 5:00 p.m. Eastern Time on September 29, 2022. The shares were distributed to their recipients on October 3. On November 3, 2022, the Company held a special meeting of shareholders during which the Company's shareholders approved a reverse stock split by any whole number in a range from 1 to 5, to 1 to 40, to be selected at the discretion of the Board of Directors. Immediately following the meeting, all shares of Series B Preferred Stock were redeemed by the Company.

Third Quarter 2022 Financial Results

As of September 30, 2022, Baudax Bio had cash and cash equivalents of $5.6 million.

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the three months ended September 30, 2022 was $0.2 million. This compares to $0.3 million for the three months ended September 30, 2021, a decrease of $0.1 million, which is the impact of the reduction in our field staff in the current year and the impact of additional sales to 340B hospitals and associated discounts in the third quarter of 2022. While utilizing the title model of distribution, product revenue is recognized as shipments are made to the Company's third-party logistics provider.

Cost of sales for the three months ended September 30, 2022 was $1.2 million, compared to $0.5 million for the three months ended September 30, 2021, an increase of $0.7 million, and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO, including supply chain and quality costs. The increase of $0.7 million was primarily a result of the increase in inventory reserve expense in the current year compared to the prior year. Certain product costs of ANJESO units recognized as revenue during the three months ended September 30, 2022 and 2021 were expensed prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the related periods.

Research and development expense for the three months ended September 30, 2022 was $0.6 million compared to $0.7 million for the three months ended September 30, 2021, a decrease of $0.1 million, which was a result of a decrease in personnel costs of $0.1 million.

Selling, general and administrative expenses for the three months ended September 30, 2022 were $3.8 million, of which $0.9 million was attributable to selling expense and $2.9 million was attributable to general and administrative expense. This compares to $11.1 million for the same prior year period, of which $5.8 million was attributable to selling

expense and $5.3 million was attributable to general and administrative expense. Selling expenses decreased $4.9 million, primarily as a result of a reduction in personnel costs of $2.7 million, a decrease in marketing costs of $1.9 million and a decrease in associated travel expenses of $0.2 million. The decrease of $2.4 million in general and administrative costs was primarily a result of a decrease in personnel costs of $1.7 million, a decrease in public company costs of $0.4 million and a decrease in consulting costs of $0.3 million.

As a result of recent events, circumstances, and probabilities, Baudax Bio evaluated the intangible asset carrying value attributed to ANJESO as of September 30, 2022 and recorded a non-cash impairment loss to reduce the carrying value of the asset to $2.0 million. In addition, due to these same events and probabilities, the value of its construction in progress related to the construction of an additional manufacturing suite for ANJESO was also reduced to $1.0 million as it is no longer planned to be used for production.

Baudax Bio reported a net loss of $29.2 million, or $(2.47) per share, including non-cash charges of $24.9 million (primarily related to the impairment loss for the carrying value reductions discussed above), for the three months ended September 30, 2022. Adjusted net loss* was $4.6 million. Net loss for the three months ended September 30, 2021 was $17.0 million, or $(7.03) per share, including non-cash charges of $5.7 million. Adjusted net loss* was $11.3 million for the three months ended September 30, 2021.

Nine Months Ended September 30, 2022 Financial Results

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the nine months ended September 30, 2022 was $1.0 million. This compares to $0.7 million for the nine months ended September 30, 2021, an increase of $0.3 million, which was attributable to increased demand at existing accounts. While utilizing the title model of distribution, product revenue is recognized as shipments are made to the Company's third-party logistics provider.

Cost of sales for the nine months ended September 30, 2022 was $2.2 million, compared to $1.9 million for the nine months ended September 30, 2021, an increase of $0.3 million, and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO, including supply chain and quality costs. The increase of $0.3 million was primarily a result of the increase in inventory reserve expense of $0.6 million, partially offset by the reduction in production and storage costs of $0.2 million. Certain product costs of ANJESO units recognized as revenue during the nine months ended September 30, 2022 and 2021 were expensed prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the related periods.

Research and development expenses for the nine months ended September 30, 2022 were $2.9 million compared to $2.6 million for the nine months ended September 30, 2021. The increase of $0.3 million was primarily due to the initiation of the pediatric trial for ANJESO of $0.3 million.

Selling, general and administrative expenses for the nine months ended September 30, 2022 were $22.0 million, of which $9.2 million was attributable to selling expense and $12.8 million was attributable to general and administrative expense. This compares to $33.8 million for the same prior year period, of which $15.9 million was attributable to selling expense and $17.9 million was attributable to general and administrative expense. Selling

expenses decreased $6.7 million, primarily as a result of a reduction in personnel costs of $3.4 million, a decrease in marketing costs of $3.1 million and a decrease in travel expenses of $0.2 million. The decrease of $5.1 million in general and administrative expenses was primarily a result of a decrease in personnel costs of $2.6 million, a decrease in public company costs of $1.8 million, and a decrease in consulting costs of $0.7 million.

Baudax Bio reported net loss of $49.5 million, or $(6.45) per share, including net non-cash charges of $24.9 million, for the nine months ended September 30, 2022. Adjusted net loss* was $24.7 million. For the nine months ended September 30, 2021 net loss was $49.2 million, or $(23.29) per share, including net non-cash charges of $15.1 million. Adjusted net loss* was $34.1 million

*** Non-GAAP Financial Measures**

To supplement the Company's financial results determined by U.S. generally accepted accounting principles ("GAAP"), the Company is reporting certain non-GAAP information for its business, including adjusted net loss. Adjusted net loss is net loss as determined under GAAP, excluding the changes in fair values of contingent consideration and warrant valuations, gain on extinguishment of debt, interest, depreciation, amortization, stock-based compensation, losses on impairment of construction in progress and intangible assets and the write off of inventory. The Company believes this non-GAAP financial measure is helpful in understanding its business as it is useful to investors in allowing for greater transparency of supplemental information used by management. This measure is used by investors, as well as management in assessing the Company's performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared. Please see the section of this press release titled "Reconciliation of GAAP to Non-GAAP Financial Measures" for a reconciliation of non-GAAP adjusted net loss to its most directly comparable GAAP measure.

About ANJESO®

ANJESO® (meloxicam) injection is a proprietary, long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase type 2 pathway (COX-2) and subsequent reduction in prostaglandin biosynthesis. ANJESO® is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. As a non-opioid, Baudax Bio believes ANJESO® has the potential to overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential, while maintaining meaningful analgesic effects for relief of pain. ANJESO® was designed using the NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on innovative products for hospital and

related settings. Baudax Bio markets ANJESO®, the first and only 24-hour, intravenous (IV) COX-2 preferential non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain. In addition to ANJESO, the Company has a pipeline of other innovative pharmaceutical assets including two clinical-stage, novel neuromuscular blocking (NMBs) agents and a proprietary chemical reversal agent specific to these NMBs. For more information, please visit www.baudaxbio.com.

Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Baudax Bio's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "goal," "intend" and "expect" and similar expressions, as they relate to Baudax Bio or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Baudax Bio as of the date of publication on this internet site and are subject to a number of risks, uncertainties, and other factors that could cause Baudax Bio's performance to differ materially from those expressed in, or implied by, these forward-looking statements. These risks and uncertainties include, among other things, risks related to market, economic and other conditions, the ongoing economic and social consequences of the COVID-19 pandemic, Baudax Bio's ability to advance its current product candidate pipeline through pre-clinical studies and clinical trials, Baudax Bio's ability to raise future financing for continued development of its product candidates such as BX1000, BX2000 and BX3000, Baudax Bio's ability to pay its debt and satisfy conditions necessary to access future tranches of debt, Baudax Bio's ability to comply with the financial and other covenants under its credit facility, Baudax Bio's ability to manage costs and execute on its operational and budget plans, Baudax Bio's ability to achieve its financial goals; Baudax Bio's ability to maintain listing on the Nasdaq Capital Market; and Baudax Bio's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. These forward-looking statements should be considered together with the risks and uncertainties that may affect Baudax Bio's business and future results included in Baudax Bio's filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to Baudax Bio, and Baudax Bio assumes no obligation to update any forward-looking statements except as required by applicable law.

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BAUDAX BIO, INC.
Consolidated Balance Sheets
(Unaudited)

(amounts in thousands, except share and per share data)

Assets	**September 30, 2022**	**December 31, 2021**
Current assets:		
Cash and cash equivalents	$ 5,647	$ 15,891
Accounts receivable, net	313	542
Inventory	4,477	5,002
Prepaid expenses and other current assets	832	2,059
Total current assets	$ 11,269	$ 23,494
Property and equipment, net	1,239	5,015
Intangible assets, net	2,000	21,678
Goodwill	2,127	2,127
Other long-term assets	875	963
Total assets	$ 17,510	$ 53,277
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	3,609	1,468
Accrued expenses and other current liabilities	3,319	5,540
Current portion of long-term debt, net	5,911	2,222
Current portion of contingent consideration	8,436	6,416
Total current liabilities	21,275	15,646
Long-term debt, net	2,175	6,309
Long-term portion of contingent consideration	12,972	17,446
Other long-term liabilities	628	650
Total liabilities	37,050	40,051
Shareholders' (deficit) equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 20,003.745 shares at September 30, 2022 (all of which shares were issued on October 3, 2022 pursuant to a stock dividend) and 8,289 shares at December 31, 2021	—	—
Common stock, $0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 20,003,745 shares at September 30, 2022 and 2,807,239 shares at December 31, 2021	200	28

Additional paid in-capital	161,914	145,287
Accumulated deficit	(181,654)	(132,089)
Total shareholders' (deficit) equity	(19,540)	13,226
Total liabilities and shareholders' (deficit) equity	$ 17,510	$ 53,277

BAUDAX BIO, INC.

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue, net	$ 238	$ 281	$ 959	$ 680
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	1,208	462	2,217	1,869
Research and development	645	658	2,850	2,623
Selling, general and administrative	3,808	11,074	22,027	33,770
Amortization of intangible assets	644	644	1,932	1,932
Change in warrant valuation	(1)	(6)	(7)	(47)
Change in contingent consideration valuation	1,222	3,829	(1,254)	9,551
Loss on impairment of property and equipment	3,662	—	3,662	—
Loss on impairment of intangible asset	17,746	—	17,746	—
Total operating expenses	28,934	16,661	49,173	49,698
Operating loss	(28,696)	(16,380)	(48,214)	(49,018)
Other expense:				
Other expense, net	(509)	(582)	(1,331)	(185)
Net loss	$ (29,205)	$ (16,962)	$ (49,545)	$ (49,203)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (2.47)	$ (7.03)	$ (6.45)	$ (23.29)
Weighted average common shares outstanding, basic and diluted	11,836,122	2,411,433	7,685,398	2,112,247

BAUDAX BIO, INC.

Reconciliation of GAAP to Non-GAAP Measures

(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(amounts in thousands)	**2022**	**2021**	**2022**	**2021**
Net loss (GAAP)	$ (29,205)	$ (16,962)	$ (49,545)	$ (49,203)
Stock-based compensation	314	925	1,172	4,132
Non-cash interest expense	203	215	652	673
Gain on extinguishment of debt	—	—	—	(1,553)
Depreciation expense	39	46	125	195
Amortization expense	644	644	1,932	1,932
Non-cash loss on retirement of fixed assets	—	—	8	—
Change in warrant valuation	(1)	(6)	(7)	(47)
Change in contingent consideration valuation	1,222	3,829	(1,254)	9,551
Loss on impairment of property and equipment	3,662	—	3,662	—
Loss on impairment of intangible asset	17,746	—	17,746	—
Write off of inventory	757	(3)	843	202
Adjusted net loss (non-GAAP)	$ (4,619)	$ (11,312)	$ (24,666)	$ (34,118)

To supplement the Company's financial results determined by U.S. generally accepted accounting principles ("GAAP"), the Company has disclosed in the tables below the following non-GAAP information about adjusted net loss.

Adjusted net loss is net loss as determined under GAAP, excluding the changes in fair values of contingent consideration and warrant valuations, gain on extinguishment of debt, interest, depreciation, amortization, stock-based compensation, losses on impairment of construction in progress and intangible assets and the write off of inventory.

The Company believes that non-GAAP financial measures are helpful in understanding its business as it is useful to investors in allowing for greater transparency of supplemental information used by management. Adjusted net loss is used by investors, as well as management in assessing the Company's performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

Source: Baudax Bio, Inc.